UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

MYRTLE THOMPSON,

Plaintiff,

v.

DEPUY ORTHOPAEDICS, INC., et al.,

Defendants.

CASE NO.: 1:13-CV-00602

Judge Michael R. Barrett

OPINION AND ORDER

This matter is before the Court on the Motion to Dismiss of Defendants DePuy Orthopaedics, Inc. and Johnson & Johnson. (Doc. 5). Plaintiff Myrtle Thompson has filed a response in opposition (Doc. 8), and Defendants have filed a reply (Doc. 9). This matter is now ripe for review.

I. FACTUAL AND PROCEDURAL OVERVIEW

A. Factual Background

The basic facts construed in the light most favorable to Plaintiff are as follow.

DePuy International, Ltd., a subsidiary of Defendant Johnson & Johnson, manufactures bone cement that is used in knee replacement surgeries. (Doc. 1, ¶¶ 8-9). The bone cement is considered a Class II medical device. (*Id.* ¶ 21). That bone cement is distributed in the United States by Defendant DePuy Orthopeadics, Inc. ("DePuy") under the trade name DePuy CMW 1 Gentamicin bone cement. (*Id.* ¶ 9).

The DePuy CMW 1 Gentamicin bone cement has been approved by the Food and Drug Administration ("FDA") through the 510(k) premarket notification process. As alleged by Plaintiff, DePuy submitted a 510(k) premarket notification for its DePuy 1 Gentamicin bone

cement on or about June 30, 2003. (*Id.* ¶ 24). The 510(k) submission indicates that "DePuy 1 Gentamicin Bone Cement is a self curing cement, to which one gram of Gentamicin is added in 40 grams of PMMA (Polymethyl methacrylate) cement for allowing the seating and securing of a metal or plastic prosthesis to living bone." (*Id.*) On or about September 29, 2003, the FDA granted marketing approval for the DePuy 1 Gentamicin Bone Cement as substantially equivalent to legally marketed predicate devices. (*Id.* ¶ 25).

On or about June 17, 2004, DePuy submitted a new 510(k) premarket notification for its DePuy 1 Gentamicin Bone Cement. (*Id.* ¶ 26). It did so because "[t]he Gentamicin Sulphate used in the cements is to be changed from micronised particles to non-micronised particles." (*Id.*) The 510(k) submission further indicates that "[b]ased on similarities in design, material, manufacturing method and intended use, DePuy believes that the DePuy 1 Gentamicin . . . manufactured with non-micronised are substantially equivalent to the previously cleared antibiotic bone cements manufactured with micronised Gentamicin." (*Id.*) On or about July 1, 2004, the FDA granted marketing approval for the DePuy 1 Gentamicin Bone Cement as amended with non-micronized antibiotic particles as substantially equivalent to legally marketed predicate devices. (*Id.* ¶ 27).

On or about October 24, 2005, DePuy submitted another new 510(k) premarket notification for its DePuy 1 Gentamicin Bone Cement. (*Id.* ¶ 28). This time, the 510(k) submission listed the DePuy 1 Gentamicin as being branded as DePuy CMW 1 Gentamicin Bone Cement and as a substantially equivalent device. (*Id.* ¶ 29). The 510(k) submission also described the DePuy CMW 1 Gentamicin Bone Cement as a "self curing cement" that "allows the seating and securing of a metal or plastic prosthesis to living bone." (*Id.*) It further identified the following modifications: "DePuy CMW 1 Gentamicin will be made available in a 20 gram

presentation in addition to the previously cleared 40 gram presentation. Changes are being made to the formulation of the bone cement liquid component." (*Id.*) On November 22, 2005, the FDA granted marketing approval for the DePuy CMW 1 Gentamicin Bone Cement as a substantially equivalent device. (*Id.* ¶ 30).

On January 22, 2009, Plaintiff Myrtle Thompson underwent left knee replacement surgery. (*Id.* ¶ 8). Plaintiff's surgeon used DePuy CMW 1 Gentamicin Bone Cement for that knee replacement surgery. (*Id.*)

Around late 2011, Plaintiff began complaining to her physician of aching and throbbing pain in her left knee. (*Id.* ¶¶ 10-11). In April 2012, a bone scan showed a loosening of the tibial component of the knee replacement for which her physician recommended knee revision surgery. (*Id.* ¶ 12). On May 24, 2012, Plaintiff underwent a total revision knee surgery. (*Id.* ¶ 13). Notes from her surgery indicate that tibial component was grossly loose and could be lifted up off the tibial cement. (*Id.* ¶ 13). Plaintiff's physician confirmed that the tibial component had loosened from the bone due to the failure of the bone cement to properly adhere to the surface. (*Id.*)

B. Procedural Background

Based upon those facts, Plaintiff alleged five causes of action against Defendants DePuy and Johnson & Johnson for: (1) strict products liability for defective manufacturing under Ohio Rev. Code § 2307.74; (2) strict products liability for design defects under Ohio Rev. Code § 2307.75; (3) strict products liability for defect due to inadequate warning under Ohio Rev. Code § 2307.76; (4) strict products liability for defect due to nonconformance with representations under Ohio Rev. Code § 2307.77; and (5) fraudulent and negligent misrepresentation. Plaintiff also sought punitive damages against Defendants. Subsequently, the parties stipulated to the

voluntary dismissal of Johnson & Johnson, and Plaintiff abandoned her claims for fraudulent and negligent misrepresentation. (Doc. 12; Doc. 8, p. 19). Accordingly, Plaintiff now proceeds against only DePuy on the four claims for strict products liability brought under Ohio Rev. Code § 2307 and on the request for punitive damages.

DePuy has moved to dismiss all remaining claims asserted against it in the Complaint on two grounds. (Doc. 5). First, DePuy contends that the strict products liability claims fail to state a plausible claim for relief under the pleading standards of *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544 (2007). Second, DePuy contends that the request for punitive damages is barred as a matter of law because the bone cement at issue is a medical device subject to the regulatory jurisdiction of the FDA.

II. LEGAL STANDARD

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint "must contain (1) 'enough facts to state a claim to relief that is plausible,' (2) more than 'a formulaic recitation of a cause of action's elements,' and (3) allegations that suggest a 'right to relief above a speculative level.'" *Tackett v. M&G Polymers, USA, LLC*, 561 F.3d 478, 488 (6th Cir. 2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009). Although the plausibility standard is not equivalent to a "'probability requirement,' . . . it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678 (quoting *Twombly*, 550 U.S. at 556). In determining whether the plausibility standard is satisfied, the Court must "'construe the complaint in the light most favorable to the plaintiff, accept its allegations as true, and draw all reasonable inferences

in favor of the plaintiff.'" *Bassett v. NCAA*, 528 F.3d 426, 430 (6th Cir. 2008) (quoting *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007)). Nevertheless, a court need not "accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555. A pleading that offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

III. STRICT LIABILITY CLAIMS

To bring a claim under the Ohio Product Liability Act ("OPLA"), the plaintiff must establish that (1) the product was defective; (2) the defect was the proximate cause of the plaintiff's harm; and (3) the manufacturer designed, formulated, produced, constructed, created, assembled, or rebuilt the actual product that was the cause of harm for which the plaintiff seeks to recover. Ohio Rev. Code § 2307.73. With respect to the first element, the defect may be one relating to the manufacture or construction, the design or formulation, a warning or instruction, or the lack of conformance to a representation. *Id.* A plaintiff may prove a defect by direct or circumstantial evidence. *Id.*

A. Manufacturing Defect Claim (Count One)

Plaintiff brings the claim for strict products liability for defective manufacturing under Ohio Rev. Code 2307.74. Section 2307.74 provides:

> A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

Ohio Rev. Code § 2307.74.

DePuy seeks to dismiss the manufacturing defect claim on the bases that Plaintiff has not plausibly alleged (1) a material deviation or the nature of the defect; (2) that the bone cement reached her in substantially the same condition; (3) that the tibial component loosened because of the bone cement; and (4) that other alternative causes could be ruled out.

Within the Sixth Circuit, multiple courts have considered when a defect claim has been plausibly pled. Generally, defect claims based on manufacture have been dismissed where the plaintiff identifies the problems experienced after using a particular product but fails to identify the nature of the alleged defect. *See Frey v. Novartis Pharmaceuticals Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009). Manufacturing defect claims have survived, however, in various circumstances. At a minimum, the district courts have required allegations that the defendant manufactured the product, that the product was used by the plaintiff, that the product failed while being used by the plaintiff, and that the portion of the product that failed could be identified and is so identified in the complaint. *See Marcum v. DePuy Orthopedics, Inc.*, No.: 1:12-cv-834, 2013 U.S. Dist. LEXIS 62875, at *13-15 (S.D. Ohio May 2, 2013) (holding that allegations that plaintiff had defendant's hip replacement parts surgically implanted, the hip replacement parts broke while implanted, that defendant's products can be identified, and that defendant was required to maintain good manufacturing practices were sufficient to allege claims for manufacturing and design defect); *Clark v. Wright Med. Tech., Inc.*, No. 3:11-cv-162, 2011 U.S. Dist. LEXIS 74248 (S.D. Ohio July 11, 2011) (alleging that defendant's product used in hip replacement, that hip failed and revision surgery was necessary, and that medical tests showed that components manufactured by defendant had fractured); *Friedman v. Intervet Inc.*, No. 3:09-cv-2945, 2010 U.S. Dist. LEXIS 71718 (S.D. Ohio July 16, 2010) (holding a plausible product liability claim had been pled where allegations detailed the specific problem with the product,

the consequences of that problem, that plaintiff used the product, and that those consequences occurred); *Foust v. Stryker Corp.*, No. 2:10-cv-00005, 2010 U.S. Dist. LEXIS 69771, at *10-12 (S.D. Ohio June 22, 2010) (holding a plausible product liability claim had been pled where the plaintiff alleged that the product was manufactured by the defendant, that the product was used by the plaintiff, that the product broke while implanted in the plaintiff, and that the defendant's products that allegedly failed could be identified in two parts by specific part number); *Redinger v. Stryker Corp.*, No. 10-cv-104, 2010 U.S. Dist. LEXIS 49465 (N.D. Ohio May 19, 2010) (holding product liability claims were sufficiently pled where the plaintiff alleged that a part related to the implant device was recalled and that the actual device broke in the plaintiff's leg). Some courts also have expressly considered the fact that the plaintiff pled specific and detailed facts from which the requisite material deviation could be inferred. *See Friedman*, 2010 U.S. Dist. LEXIS 71718; *Redinger*, 2010 U.S. Dist. LEXIS 49465; *Stratford v. SmithKline Beechmam Corp.*, No. 2:07-cv-639, 2008 U.S. Dist. LEXIS 84826, at *21 (S.D. Ohio June 17, 2008).

Here, Plaintiff's Complaint adequately pleads facts to make her manufacturing defect claim plausible. Plaintiff specifically pleads that DePuy obtained approval from the FDA for marketing the bone cement under "the trade name DePuy CMW 1 Gentamicin bone cement" and that DePuy "distributed" the bone cement in the United States "under the trade name DePuy CMW 1 Gentamicin bone cement." (Doc. 1, ¶¶ 9, 22-30).[1] Plaintiff further alleges that the product was defective when it left the hands of the manufacturer, and that it reached Plaintiff on January 22, 2009 when it was used for her left knee replacement surgery. (*Id.* ¶¶ 8, 9, 45).

[1] "Suppliers" may be liable under the OPLA, as if they were a manufacturer, under certain circumstances. As is relevant here, a supplier may be liable as if it were the manufacturer of the product when "[t]he supplier in question marketed that product under its own label or trade name." Ohio Rev. Code § 2307.78(B)(7). A supplier is defined as a "person that, in the course of a business conducted for the purpose, sells, distributes, leases, prepares, blends, packages, labels, or otherwise participates in the placing of the product in the stream of commerce." Ohio Rev. Code § 2307.71(15)(a)(i). Plaintiff's allegations make it plausible that DePuy was a supplier that marketed the bone cement under its own label or trade name.

Moreover, Plaintiff identifies the previously implanted tibial component as the component that loosened from the bone, and identifies the DePuy cement, and in particular, the use of non-micronized particles, the change in the liquid component and the failure to adequately test the results of those changes, as the reasons for that failure. (*Id.* ¶¶ 13, 47-49). She further alleges that her physician noted the failure, and that operative reports noted that the tibial component "could be lifted up off the tibial cement." (*Id.*) She alleges that she learned that the component had loosened from the bone after her complaints of persistent aching and throbbing in her left knee, after an x-ray showed her knee replacement device was in good position, and after subsequently undergoing a bone scan that showed the loosening. (*Id.* ¶¶ 11-12). As a result of the loosening, she underwent total revision knee surgery. (*Id.* ¶ 13). Plaintiff alleges that the loosening was unexpected and premature, and caused her permanent damage and weakness. (*Id.* ¶ 17). She also pleads and references good manufacturing practices that are to be maintained. (*Id.* ¶¶ 35-36). These facts are incorporated into each of Plaintiff's counts and go beyond a mere recitation of the cause of actions elements that have been found insufficient to state a claim for relief.

DePuy's assertion that Plaintiff had to, but did not, allege facts sufficient to show the product reached her in substantially the same condition is not well taken. Not only does DePuy attempt to introduce, without explanation, facts not contained within the Complaint, but DePuy also fails to cite any authority that indicates the combination of the liquid and powder components means that the product could never reach the patient in substantially the same condition. While courts have held that a "'substantial alteration subsequent to the manufacture and sale of the product will relieve the defendant-manufacturer from liability[,]'" they have defined substantial alteration as a change that "'increases the likelihood of malfunction,'" "'is the

proximate cause of the harm complained of'" and is "'independent of the expected and intended use to which the product is put.'" *Aldridge v. Reckart Equip. Co.*, No. 04CA17, 2006 Ohio App. LEXIS 4904, at *21 (4th App. Dist. Sept. 19, 2006) (quoting *Cox v. Oliver Machinery Co.*, 41 Ohio App. 3d 28, 30-31 (12th App. Dist. 1987); *Kobza v. General Motors Corp.*, 63 Ohio App. 3d 742, 745 (8th App. Dist. 1989)); *see also Marcum*, 2013 U.S. Dist. LEXIS 62875, at *14-15 (citing *Alridge*, 2006 Ohio App. LEXIS 4904, at *21). Here, even if the product required a combination of a powder and liquid component, the mere use of the product after combining those components does not make the change independent of the expected and intended use. Although it is possible that the evidence may eventually show that a substantial alteration existed that created the alleged problem, Plaintiff does not need to set forth specific facts beyond her current allegations to disprove a substantial alteration and to avoid a Rule 12(b)(6) dismissal. *See Foust*, 2010 U.S. Dist. LEXIS 69771, at *11-12 (citing *Redinger*, 2010 U.S. Dist. LEXIS 49465) (holding that the fact that the plaintiff's hip replacement parts may have failed for multiple reasons was relevant to proving claims but not to determining whether the claim was plausible at the motion to dismiss stage).

Similarly, DePuy's argument that Plaintiff has not alleged facts that rule out alternative causes does not require dismissal of Plaintiff's defective manufacturing claim. *See Foust*, 2010 U.S. Dist. LEXIS 69771, at *11-12 (citing *Redinger*, 2010 U.S. Dist. LEXIS 49465). While DePuy points out that the same lot of bone cement was used for all components of the total knee replacement but only the tibial component failed, DePuy's argument improperly places upon Plaintiff the burden of pleading a *probable* rather than a *plausible* claim.[2] Considering that facts

[2] Although DePuy also argues that the change to the non-micronised particles cannot be the basis for the claim because a change in antibiotic powder particle size affects the release of the drug and not the adherence, those statements are unsupported evidence outside of the Complaint. (Doc. 9, p. 6). Those statements thus are not properly considered in ruling on a motion to dismiss.

may exist that explain why the bone cement, although purportedly defective, did not fail to adhere to other components and that Plaintiff has set forth more than a bare recitation of the cause of actions elements, the Court concludes that Plaintiff has set forth a plausible claim based upon a manufacturing defect.

B. Defective Design (Count Two)

Plaintiff brings the claim for strict products liability for defective design under Ohio Rev. Code § 2307.75. Section 2307.75 provides, in pertinent part:

> [A] product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation . . . .

Ohio Rev. Code § 2307.75(A). That section further sets forth factors to be considered in balancing the foreseeable risks and the benefits associated with the design or formulation. Ohio Rev. Code § 2307.75(B)-(C). Yet, a product cannot be defective in design or formulation under that section "if that harm . . . was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community." Ohio Rev. Code § 2307.75(E). A product also cannot be defective in design or formulation when "at the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which the claimant seeks to recover . . . without substantially impairing the usefulness or intended purposes of the product." Ohio Rev. Code § 2307.75(F).

DePuy seeks to dismiss the design defect claim on the bases that Plaintiff has not plausibly alleged (1) the requisite elements of the claim or the nature of the defect; (2) that the

bone cement reached her in substantially the same condition; (3) that the tibial component loosened because of the bone cement; (4) the inherent characteristics and other alternative causes could be ruled out; and (4) there existed other feasible alternative designs.

Similar to the manufacturing defects, courts in the Sixth Circuit generally have dismissed design defect claims where the plaintiff merely sets forth the elements of the claim without specific allegations as to the alleged defect. *See, e.g.*, *Liming v. Stryker Corp.*, No. 1:11-cv-788, 2012 U.S. Dist. LEXIS 75509, at *13 (S.D. Ohio May 31, 2012) (dismissing design defective claim because the complaint "merely regurgitates, nearly verbatim, the elements of a defective design claim . . . [and] contains no substantive, specific factual allegations with respect to the design of the pain pump from which the Court could plausibly infer a strict liability design defect cause of action"); *Frey*, 642 F. Supp. 2d at 795 (dismissing the plaintiff's design defect claim "because plaintiffs have once again simply provided a formulaic recitation of the elements" and have not "alleged any facts that would permit the Court to conclude that there was a defect in the design or formulation"). Design defect claims have survived, however, in various circumstances. At a minimum, the district courts have required allegations that the defendant manufactured or designed the product, that the product was used by the plaintiff, that the product failed while being used by the plaintiff, and that the portion of the product that failed could be identified and is so identified in the complaint. *See Marcum*, 2013 U.S. Dist. LEXIS 62875, at *15; *Clark*, 2011 U.S. Dist. LEXIS 74248, at *5-6; *Foust*, 2010 U.S. Dist. LEXIS 69771, at *10-12. Some district courts have relied on the fact that the product at issue had been recalled when determining that the plaintiff had raised a plausible inference that the foreseeable risks associated with the design or formulation of the product outweighed the benefits. *Friedman*, 2010 U.S. Dist. LEXIS 71718, at *12-13; *Redinger*, 2010 U.S. Dist. LEXIS 49465, at *7. Nevertheless, a

plaintiff is not required to set forth specific facts addressing the multi-factor balancing test set forth in Ohio Rev. Code § 2307.75 to survive a motion to dismiss. *Boroff v. Alza Corp.*, 685 F. Supp. 2d 704, 709 (N.D. Ohio 2010); *see also Alridge*, 2006 Ohio App. LEXIS 4904, at *32 ("Foreseeable uses of a product, foreseeable risks associated with a product, benefits associated with a product, and consumer expectations regarding a product's uses and risks are ordinarily all factual questions" and a "determination whether a design defect exists involves a balancing of these factual issues.").

For many of the same reasons set forth above with respect to the manufacturing defect claim, the Court concludes that Plaintiff has sufficiently pled a claim for design defect. As explained previously, Plaintiff has alleged supplier liability as well as multiple specific facts that identify the problems she experienced and why she contends the bone cement was the root of those problems. Plaintiff's factual allegations in the Complaint also sufficiently put DePuy on notice that the safety risks at issue are the failure of the bone cement to properly adhere to the bone or prosthetic device and the premature loosening of the bone cement as a result of changes made to the bone cement, which cause further permanent impairments and weaknesses, and require the patient to undergo premature revision surgery. The extent to which those risks are foreseeable and outweigh the benefits associated therewith requires the Court to make fact-specific inquiries that are not appropriate at this stage of the litigation.

With respect to the substantially same condition argument and causation arguments that were addressed in regards to the manufacturing defect claim, the Court incorporates its above analysis here.

DePuy's final arguments specific to the design defect claim are that Plaintiff did not sufficiently plead facts that plausibly eliminate the inherent characteristics of the product as the

cause or that plausibly show that an alternative design or formulation was not available. The Court, however, disagrees. Plaintiff has alleged that DePuy changed the design from the micronized particles to the non-micronized particles and made a change to the liquid component, and that those changes made the product defective. Those allegations, construed in favor of Plaintiff, raise the reasonable inference that her injuries were caused a change in design, not by an inherent characteristic of the product, and that a practical and feasible alternative design exists (i.e., the bone cement with the micronised particles and without the change to the liquid component) that may prevent the harm. Accordingly, Plaintiff has sufficiently pled a plausible claim based upon design defect.

C. Inadequate Warning (Claim Three)

Plaintiff brings the claim for strict products liability based upon inadequate warnings under Ohio Rev. Code § 2307.76. Section 2307.76 provides, in pertinent part:

> [A] product is defective due to inadequate warning or instruction if either of the following applies:
>
> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76.

DePuy contends that Plaintiff's inadequate warning claim should be dismissed because the learned intermediary doctrine is applicable, and Plaintiff did not allege a single warning that DePuy should have provided the surgeon that would have persuaded him to choose a different bone cement. The Court disagrees.

The learned intermediary doctrine does not automatically "'relieve the manufacturer of liability to the ultimate user for an inadequate or misleading warning.'" *Vaccariello v. Smith & Nephew Richards, Inc.*, 94 Ohio St. 3d 380, 384 (2002) (quoting *Tracy v. Merrell Dow Pharmaceuticals, Inc.*, 58 Ohio St. 3d 147, 149-50 (1991)). It "'only provides that the warning reaches the ultimate user through the learned intermediary.'" *Vaccariello*, 94 Ohio St. 3d at 384 (quoting *Tracy*, 58 Ohio St. 3d at 150). Only when the manufacturer provides the learned intermediary with an adequate warning will the manufacturer's duty be discharged. *DeGidio v. Centocor Ortho Biotech, Inc.*, No. 3:09-cv-721, 2010 U.S. Dist. LEXIS 118406, at *14 (N.D. Ohio Nov. 5, 2010).

Here, the issue raised is whether Plaintiff's allegations plausibly show that the information at issue did not reach her or her physician.[3] The Court finds that her allegations adequately make that showing. Plaintiff alleges that DePuy knew or should have known about the risk that the bone cement would not adhere to the bone or prosthetic device and knew or should have known that the failure to adhere would cause injury and require revision surgery. (Doc. 1, ¶¶ 67-68). She further alleges that no warnings were provided by DePuy about those risks. (*Id.*) Construing those allegations in Plaintiff's favor, the alleged lack of any warning plausibly shows that the warning did not reach the physician or the patient as is necessary for the learned intermediary doctrine to be applicable. Whether the physician would have changed his prescribing conduct goes to the issue of proximate cause, which is not properly decided on a motion to dismiss where, as here, the allegations give rise to at least a plausible inference that the physician may have changed course upon receiving the requisite warnings. *See DeGidio*, 2010

[3] DePuy does not set forth any specific argument as to why the warnings given were adequate and were not misleading.

U.S. Dist. LEXIS 118406, at *14. Accordingly, Plaintiff has sufficiently alleged a claim based upon inadequate warning. *Liming*, 2012 U.S. Dist. LEXIS 75509, at *13.[4]

D. Non-Conformance with Representations (Claim Four)

Plaintiff brings the claim for strict products liability based upon non-conformance with representations under Ohio Rev. Code § 2307.77. Section 2307.77 provides:

> A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

Ohio Rev. Code § 2307.77. To recover under this section, a plaintiff must prove that: (1) the defendant made a representation as to material fact concerning the character or quality of the product; (2) the product failed to conform to that representation; (3) the plaintiff and/or her physician justifiably relied on that representation; and (4) the reliance by plaintiff and/or her physician on the defendant's representations was the direct and proximate cause of the plaintiff's injuries. *Cervelli v. Thompson/Center Arms*, 183 F. Supp. 2d 1032, 1045 (S.D. Ohio 2002). Where the plaintiff fails to identify a representation made about the product, the claim for non-conformance with the representation must fail. *Id.*

DePuy contends that Plaintiff's claim for non-conformance with representations should be dismissed on the bases that Plaintiff has not plausibly alleged (1) any of the requisite elements of the claim; (2) that the bone cement reached her in substantially the same condition; (3) that the tibial component loosened because of the bone cement; and (4) how a different representation would have persuaded her surgeon to choose a different bone cement. The Court disagrees.

[4] To the extent DePuy intended to raise with respect to this claim any of the arguments addressed in regards to other claims, the Court incorporates its analyses of those arguments here.

Plaintiff's Complaint adequately pleads facts that state a plausible claim based upon non-conformance with representations. The representations relied upon by Plaintiff are more than an affirmation of the value of goods, the seller's opinion, or a commendation of the goods that is not actionable. *See Jordan v. Paccar, Inc.*, 37 F.3d 1181, 1185 (6th Cir. 1994) (quoting Ohio Rev. Code Ann. § 1302.26(B)). Plaintiff instead relies on a representation made by DePuy that the bone cement was "safe for use in knee replacement surgery" despite the allegedly known harm of injury, pain, and revision surgery resulting from the failure of the bone cement to properly adhere to the bone or prosthetic device and the premature loosening of the cement as a result of changes made thereto. *See Liming*, 2012 U.S. Dist. LEXIS 75509, at *12-13 (allegations that the defendant represented to the plaintiff's surgeon that the product was safe for use in the joint space and that it was actually unsafe was sufficient to survive a motion to dismiss); *Gawloski v. Miller Brewing Co.*, 96 Ohio App. 3d 160, 167-168 (9th App. Dist. 1994) (indicating it would be sufficient for the plaintiff to allege the defendant made a representation that the product was safe even though there are risks associated with the normal use that are not generally known and recognized).[5] Plaintiff also describes DePuy's representations as to the characteristics of its products as "self-curing cement," as allowing the "seating and securing of a metal or plastic prosthesis to living bone," and as being "substantially equivalent to the previously cleared antibiotic bone cements manufactured with micronised Gentamicin." (Doc. 1, ¶¶ 26, 28). Even though Plaintiff does not utilize the exact language of DePuy's representations, her allegations permit the plausible inference that a representation was made and the bone cement did not conform to that representation. *Liming*, 2012 U.S. Dist. LEXIS 75509, at *12; *see also Lefker v. I-Flow Corp.*, No. 1:10-cv-350, 2010 U.S. Dist. LEXIS 121624, at *10-11 (S.D. Ohio Nov. 17,

[5] Whether the harm alleged is generally known and recognized is an issue that is not raised here and thus is not appropriate for resolution on the motion to dismiss. *See Gawloski*, 96 Ohio App. 3d at 167.

2010).[6] Moreover, Plaintiff alleges that she and/or her physician justifiably relied upon the representations in choosing DePuy's product for use in her original knee replacement surgery and that the representations were false because the bone cement did not sufficiently adhere to the bone and prematurely loosened on the tibial component, which led to her having the total revision surgery.

The Court is not persuaded by DePuy's argument that Plaintiff insufficiently pled that her surgeon would have chosen a different bone cement if those representations had not been made. As courts in this circuit have recognized, a "'plaintiff will not be thrown out of court for failing to plead facts in support of every arcane element of his claim'" but she must include facts that if existed would "'clearly dominate the case.'" *Lefker*, 2010 U.S. Dist. LEXIS 121624, at *9 (quoting *Scheid v. Fanny Farmer Candy Shops, Inc.*, 859 F.2d 434, 437 (6th Cir. 1988)). This is not such an issue that would plainly dominate the case. In any event, Plaintiff's factual allegations as to the representations made by DePuy, the use of the DePuy bone cement for her surgery, and the lack of conformance with the representations raise at least a plausible inference that the surgeon would have made a different decision if DePuy had not made those representations.

As for the substantially same condition argument and the causation arguments that were addressed with respect to the manufacturing defect claim, the Court incorporates its above analysis here. Accordingly, Plaintiff has sufficiently pled a plausible claim for strict liability based upon the non-conformance with representations.

IV. PUNITIVE DAMAGES

[6] DePuy's reliance on *Liming*, 2012 U.S. Dist. LEXIS 75509, at *10, is misplaced. The quotation upon which it relies (Doc. 9, p. 11) to support its argument that Plaintiff did not allege sufficient factual detail to survive dismissal, was made in the context of the plaintiff's fraud claim, and not the strict liability claim based upon non-conformance with representations. Indeed, in contrast to the fraud claim, the *Liming* court determined that claim for non-conformance with representations survived dismissal. *See Liming*, 2012 U.S. Dist. LEXIS 75509, at *12.

Plaintiff requests punitive damages on all of her strict liability claims. (Doc. 1, ¶¶ 52, 64, 70, 76). DePuy contends that the request is barred under Ohio law that precludes an award of punitive damages in connection with a product liability claim when the product allegedly causing the harm "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the 'Federal Food, Drug, and Cosmetic Act[.]" Ohio Rev. Code § 2307.80(C)(1).

While there is no question that DePuy received the requisite 510(k) approval for the bone cement, the facts alleged by Plaintiff are sufficient to show a plausible lack of compliance with the manufacturing and labeling requirements. As explained previously, Plaintiff pleads that, contrary to the requirements of the 510(k) approval process, the bone cement was adulterated because the product deviated from performance standards, that DePuy failed to establish and maintain good manufacturing practices, and that as a result of DePuy's failure to maintain such standards and practices, the bone cement failed and caused Plaintiff harm. Construing the allegations in the Complaint in light most favorable to Plaintiff, those allegations are sufficient to plead a plausible claim for punitive damages.

V. CONCLUSION

For the foregoing reasons, Depuy's Motion to Dismiss (Doc. 5) is **DENIED**. The case shall proceed as scheduled against DePuy. If the parties desire to amend the calendar, a motion to amend the current calendar order containing new proposed deadlines shall be submitted to the Court within twenty (20) days of this Opinion and Order.

IT IS SO ORDERED.

s/Michael R. Barrett
Michael R. Barrett, Judge
United States District Court